

Translation

PATENT COOPERATION TREATY

PCT/JP2003/011972



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FP2613PCT	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/JP2003/011972	International filing date (day/month/year) 19 September 2003 (19.09.2003)	Priority date (day/month/year) 19 March 2003 (19.03.2003)	
International Patent Classification (IPC) or national classification and IPC G01N 33/50, 33/48			
Applicant HAMAMATSU FOUNDATION FOR SCIENCE AND TECHNOLOGY PROMOTION			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
 - ☒ Box No. I Basis of the report
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☐ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 05 July 2004 (05.07.2004)	Date of completion of this report 06 January 2005 (06.01.2005)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/011972

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/11972

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	4-12	YES
	Claims	1-3	NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: Hiroki Nakagawa, Biotesting Illustrated, 2. Idenshi Kaisetsu no Kiso, Shujunsha Co., Ltd., 26 September, 1995, pages 153 to 166.

Document 2: CARCINOGENESIS, VOL. 19, NO. 2 91998), p. 253-157.

Document 3: CANCER RESEARCH, VOL. 55, NO. 17, 1995), p. 3785-3789.

Document 4: Japanese Journal of Gastroenterology, Vol. 99, Special Extra Issue, 20 September, 2002, page A634, Sho P-379.

Claims 1 to 3

Document 1 cited in the ISR describes a method for preparing a RNA sample without a process of cell component separation by freezing the sampled biological sample and homogenizing in the presence of a guanidine salt, in the same manner as in the embodiment of the specification of the present application (see "2. AGPC Method").

Therefore, the inventions of claims 1 to 3 do not appear to possess novelty based on document 1.

Claims 4, 5

Document 2 cited in the ISR describes a process comprising the steps of extracting RNA from an excrement sample and conducting colon cancer detection from the inversely transferred cDNA.

Therefore, using the preparation method described in document 1 when the RNA extraction is conducted from an excrement sample, thereby obtaining the configuration of the inventions described in claims 4 and 5, could have easily been conceived by a person skilled in the art.

Therefore, the inventions of those claims do not appear to involve an inventive step.

Claim 6

Document 3 cited in the ISR describes that COX-2 is a colon cancer marker, and making the measurement target COX-2 could have easily been conceived by a person skilled in the art.

Therefore the invention of claim 6 does not appear to involve an inventive step.

Claims 7 to 12

Employing the reagents used for preparation and detection in the form of a kit can be appropriately made by a person skilled in the art.

Therefore, the inventions of claims 7 to 12 do not appear to involve an inventive step.

Further, document 4 cited in the ISR describes conducting colon cancer detection by inversely transferring RNA prepared from a frozen excrement sample and preparing COX-2.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

(1) The inventions of claims 7 to 12 relate to a kit. However, what elements are comprised in the "kit" is not clear and these claims are ambiguous.